

**JOHN WOODS, M.D. and,  
TOM MCDONALD, M.D.,**

**V.**

**LORETTA E. LYNCH, United States  
Attorney General, et al.,**

**No. 1:16-CV-01289-STA-egb**

## BACKGROUND

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No. 1-3). Plaintiffs have also provided additional affidavits in support of their Motion for Preliminary Injunctions (ECF Nos. 18-2, 18-3). Defendants did not contest these allegations at the hearing or in any other filing with the Court. As such, the Court finds them undisputed for purposes of deciding Plaintiffs' Motion for a Preliminary Injunction.

According to the Amended Complaint, both Plaintiffs are licensed physicians with practices at the Henderson County Community Hospital. Both Plaintiffs are employed by EmCare, a third-party medical staffing agency which is not a party to this suit. Plaintiffs are the HCCH's only hospitalists, meaning they are the only physicians with admitting privileges for any patient at HCCH and not just their own patients. Dr. McDonald currently serves as HCCH's chief of staff and medical director.

Both Plaintiffs have previously surrendered their DEA registrations. Dr. Woods surrendered his DEA registration in 2012 as the result of an opiate addiction and resumed his medical practice with full prescribing authority in 2013. Dr. Woods has practiced continuously at HCCH since April 2015. Prior to beginning his practice at HCCH, Dr. Woods notified the DEA that he would begin practicing at HCCH but was never told he needed a waiver to do so. Dr. McDonald surrendered his DEA registration in 1999 due to a chemical dependency and then had his full prescribing authority restored in 2002. Dr. McDonald has worked at HCCH since 2002. During that time, the DEA has never required Dr. McDonald to have a waiver to continue his employment at HCCH. Plaintiffs allege that on November 10, 2016, the DEA advised both of them they were required to have a waiver from the DEA in order to work at HCCH and that neither could resume work at HCCH until an application was made for a waiver and the DEA had granted the waiver.

Based on these factual allegations, Plaintiffs seek injunctive relief. Plaintiffs argue that they have a strong likelihood of success on the merits of their claims for laches, the improper retroactive application of an administrative regulation, and an arbitrary and capricious administrative action subject to review under the Administrative Procedures Act. Plaintiffs contend that Defendants' actions will cause them irreparable harm because Plaintiffs are barred from recovering money damages against Defendants. Furthermore, Defendants' actions will cause harm to others and undermine the public interest in having practicing hospitalists at HCCH. Therefore, the Court should enjoin Defendants from stopping Plaintiffs from performing their regular duties at HCCH.

On November 15, 2016, the United States Magistrate Judge held an *ex parte* hearing on Plaintiffs' request for a temporary restraining order and issued a report and recommendation (ECF No. 11) later the same day, recommending that the Court grant the TRO. The Court then granted Plaintiffs' motion to adopt the report and recommendation immediately and issued a TRO (ECF No. 13), preventing Defendants from enforcing 21 C.F.R. § 1301.76(a) against Dr. Woods and Dr. McDonald and thereby precluding Plaintiffs from performing their duties as physician-hospitalists at the HCCH. The Court set an expedited hearing for November 29, 2016, and granted Defendants' motion to continue the hearing to December 6, 2016. The Court extended the TRO through that date.<sup>1</sup> As previously noted, the United States Attorney reported at the December 6, 2016 hearing that Defendants did not oppose the preliminary injunction.

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<sup>1</sup> Plaintiffs filed a Second Amended Complaint (ECF No. 22) on December 2, 2016. The new pleading does not appear to contain any new factual allegations. However, Plaintiffs have included in the new pleading a prayer for declaratory relief and a request for a permanent injunction.

## **STANDARD OF REVIEW**

Rule 65(d) of Federal Rules of Civil Procedure requires that every order granting an injunction must “(A) state the reasons why it issued; (B) state the terms specifically; and (C) describe in reasonable detail—and not by referring to the complaint or other document—the act restrained . . . .”<sup>2</sup> “Judges have authority to enter injunctions against a party—to change the party’s behavior through the power of the federal courts—when they have done something wrong, and even then that will not always suffice by itself.”<sup>3</sup> A preliminary injunction is “one of the most drastic tools in the arsenal of judicial remedies.”<sup>4</sup> In deciding a motion for a preliminary injunction, courts consider the following factors: (1) whether the movant has shown a strong likelihood of success on the merits; (2) whether the movant will suffer irreparable harm if the injunction is not issued; (3) whether the issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuing the injunction.<sup>5</sup> Although no one of the four factors controls, “a finding that there is simply no likelihood of success on the merits is usually fatal.”<sup>6</sup>

Rule 65(a) provides that a “court may issue a preliminary injunction only on notice to the adverse party.”<sup>7</sup> The Sixth Circuit has interpreted the notice requirement to “impl[y] a hearing in

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<sup>2</sup> Fed. R. Civ. P. 65(d).

<sup>3</sup> *Hearring v. Sliwowski*, 806 F.3d 864, 867 (6th Cir. 2015) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 32 (2008)).

<sup>4</sup> *Farnsworth v. Nationstar Mortg., LLC*, 569 F. App’x 421, 425–26 (6th Cir. 2014) (quoting *Bonnell v. Lorenzo*, 241 F.3d 800, 808 (6th Cir. 2001)).

<sup>5</sup> *Wilson v. Gordon*, 822 F.3d 934, 952 (6th Cir. 2016) (citing *City of Pontiac Retired Emps. Ass’n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (en banc)).

<sup>6</sup> *Gonzales v. Nat’l Bd. of Med. Exam’rs*, 225 F.3d 620, 625 (6th Cir. 2000).

which the defendant is given a fair opportunity to oppose the application and to prepare for such opposition.”<sup>8</sup> Because of the extraordinary nature of injunctive relief,<sup>9</sup> “the proof required . . . is much more stringent than the proof required to survive a summary judgment motion.”<sup>10</sup> Nevertheless, “a hearing is only required when there are disputed factual issues, and not when the issues are primarily questions of law.”<sup>11</sup> Where there are no material facts in dispute, the Court need not convene a full evidentiary hearing.<sup>12</sup>

### **ANALYSIS**

The Court finds that all of the factors weigh in favor of issuing a preliminary injunction. First, Plaintiffs have shown a likelihood of success on the merits of at least one of their claims. Plaintiffs proceed on three separate theories: laches, the improper retroactive application of an administrative regulation, and an arbitrary and capricious administrative action subject to review under the Administrative Procedures Act. Plaintiffs specifically challenge the DEA’s application of the regulations implementing the Controlled Substances Act. “Under 21 U.S.C. § 823(b), distributors of controlled substances must be registered by the Attorney General.”<sup>13</sup> The

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<sup>7</sup> Fed.R.Civ.P. 65(a)(1).

<sup>8</sup> *Certified Restoration Dry Cleaning Network, LLC v. Tenke Corp.*, 511 F.3d 535, 552 (6th Cir. 2007) (quoting *County Sec. Agency v. Ohio Dept. of Commerce*, 296 F.3d 477, 484 (6th Cir. 2002)).

<sup>9</sup> *Am. Civil Liberties Union Fund of Mich. v. Livingston Cnty.*, 796 F.3d 636, 642 (6th Cir. 2015) (describing preliminary injunctions as “extraordinary and drastic remedies”).

<sup>10</sup> *Leary v. Daeschner*, 228 F.3d 729, 739 (6th Cir. 2000).

<sup>11</sup> *Tenke Corp.*, 511 F.3d at 552 (citing *See Lexington–Fayette Urban County Gov’t v. BellSouth Telecomm., Inc.*, 14 F. App’x 636, 639 (6th Cir. 2001)).

<sup>12</sup> *Id.* at 553.

<sup>13</sup> *Bzdzuich v. U.S. Drug Enforcement Admin.*, 76 F.3d 738, 741 (6th Cir. 1996).

Controlled Substances Act's implementing regulations at 21 C.F.R. § 1301.76(a) prohibit a controlled substances registrant from employing "as an agent or employee who has access to controlled substances, any person who has . . . surrendered a DEA registration for cause."<sup>14</sup> DEA has discretion to allow exceptions when a person makes a written request to DEA for an exception to 21 C.F.R. § 1301.76(a), or any other regulation promulgated under the Controlled Substances Act, "stating the reasons for such exception."<sup>15</sup> Plaintiffs have shown through their affidavits that each of them voluntarily surrendered their DEA registrations while undergoing treatment for addiction or chemical dependence. Plaintiffs have further shown that each of them subsequently petitioned DEA to restore their DEA registrations with full prescribing authority. DEA granted those petitions and was at all times aware of each physician's practice at HCCH. Plaintiffs now allege that Defendants should not be able to deprive them of the opportunity to practice at HCCH pending the disposition of Plaintiffs' and/or HCCH's application for an employment waiver from the DEA.

The Court finds that Plaintiffs' proof shows a likelihood of success on the merits as to their laches claim.<sup>16</sup> "Laches is the negligent and unintentional failure to protect one's rights."<sup>17</sup>

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<sup>14</sup> 21 C.F.R. § 1301.76(a). The regulation defines "for cause" to mean "a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances." Plaintiffs allege that DEA has advised them that Plaintiffs are within the class of registrants described in § 1301.76(a). However, there is no evidence before the Court to show that Dr. Woods or Dr. McDonald previously surrendered their DEA registrations "for cause," as the regulation defines the term.

<sup>15</sup> 21 C.F.R. § 1307.03.

<sup>16</sup> It appears that HCCH has applied for an appropriate waiver from DEA, though it is not clear whether Plaintiffs have also made requested a waiver. Without some proof that Plaintiffs have made their own individual petitions for waivers, the Court has some doubt as to Plaintiffs' standing to pursue claims under the APA for the DEA's interpretation or application of 21 C.F.R. § 1301.76(a) in the context of Plaintiffs' employment at HCCH. *See Bzdzuich*, 76 F.3d at 742 (holding that a pharmacy owner, and not the pharmacist, had standing to challenge the DEA's

Generally, a party asserting laches must show “(1) lack of diligence by the party against whom the defense is asserted, and (2) prejudice to the party asserting it.”<sup>18</sup> In this case Plaintiffs’ laches theory appears to be that DEA failed to act with diligence to enforce 21 C.F.R. § 1301.76(a) against Plaintiffs, even though DEA had granted Plaintiffs DEA registrations with full prescribing authority and had knowledge of Plaintiffs’ medical practices at HCCH. As a result, the DEA should not be allowed to take administrative action against them now to deprive Plaintiffs of their ability to work at HCCH. Plaintiffs have shown that each of them had practiced at HCCH for some time, in Dr. McDonald’s case for over 14 years, and were only advised in November 2016 that they could not practice at the hospital without a waiver from DEA. Other evidence shows that DEA only began in 2014 to require employment waivers for registrants who had surrendered their DEA registrations for cause,<sup>19</sup> at a time when both Plaintiffs were practicing with full prescribing authority and with no prior notice of the need to seek a waiver.

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decision to deny a waiver of 21 C.F.R. § 1301.76(a)); *see also Bonds v. Tandy*, 457 F.3d 409, 415 (5th Cir. 2006) (holding that a pharmacist lacked prudential standing to seek judicial review of the DEA’s administrative decision to deny the pharmacist’s employer a waiver of § 1301.76(a)).

At this early stage of the proceedings, neither party has raised the issue of standing. Even though the Court has an independent obligation to consider a party’s standing, the Court need not reach Plaintiffs’ standing to decide whether a preliminary injunction should issue. Therefore, the Court declines to address it further at this time.

<sup>17</sup> *Kehoe Component Sales Inc. v. Best Lighting Prods., Inc.*, 796 F.3d 576, 584 (6th Cir. 2015) (quoting *Nartron Corp. v. STMicroelectronics, Inc.*, 305 F.3d 397, 408 (6th Cir. 2002)).

<sup>18</sup> *Id.*

<sup>19</sup> The Controlled Substances Act’s implementing regulations at 21 C.F.R. § 1307.03 permit “any person” to apply for a waiver from DEA. The regulation was listed in the Code of Federal Regulations long before 2014. Plaintiffs allege, however, that DEA advised them the agency only began in 2014 to enforce the regulation against registrants who had surrendered their DEA registration for cause.

The Court finds that this proof establishes Defendants' lack of diligence in taking administrative action against Plaintiffs. Plaintiffs have also shown that the interruption in their medical practice will cause Plaintiffs prejudice in the form of loss of income. This evidence satisfies Plaintiffs' burden to prove the elements of laches. Having concluded that Plaintiffs have established a likelihood of success on the merits of their laches claim, the Court need not decide whether Plaintiffs could also establish their related claims based on improper retroactivity or the APA.

Second, Plaintiffs have shown that they will suffer irreparable injury if the Court denies them injunctive relief. According the United States Attorney, HCCH has applied for the necessary waivers with DEA, and the agency is likely to grant the waivers. Defendants believe that Dr. Woods's waiver will be granted on an expedited basis; Dr. McDonald's waiver may take additional time simply because of the length of his tenure at HCCH. Should the Court allow Defendants to deny Plaintiffs the right to practice at HCCH pending the outcome of the waiver process, Plaintiffs will lose the opportunity to work and earn income during the interim. As the Magistrate Judge noted in his report and recommendation, harm of this nature under the circumstances is irreparable.<sup>20</sup> Therefore, this factor also weighs in favor of a preliminary injunction.

The remaining equitable factors likewise weigh in favor of injunctive relief to preserve the status quo. Plaintiffs argue that the injunction will not harm others and that if Defendants can deny Plaintiffs the opportunity to work as HCCH's only hospitalists until DEA acts on the

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<sup>20</sup> *Feinerman v. Bernardi*, 558 F. Supp.2d 36, 51 (D.D.C. 2008) ("But where, as here, the plaintiff in question cannot recover damages from the defendant due to the defendant's sovereign immunity, any loss of income suffered by the plaintiff is irreparable *per se*."); *Caspar v. Snyder*, 77 F. Supp.3d 616, 641 (E.D. Mich. 2015) ("Where the availability of a money damage remedy is significantly in doubt because of an immunity defense, money damages are not deemed an adequate remedy, rendering the harm irreparable.").



waiver application, then the people served by HCCH, including Plaintiffs' current patients, will suffer harm. The Court also finds no evidence that a preliminary injunction will cause substantial harm to others. But without an injunction, Plaintiffs' patients at HCCH and others who depend on access to HCCH for their health care will likely suffer. Therefore, all of the equitable factors weigh in favor of granting Plaintiffs a preliminary injunction.

For all of these reasons, Defendants are hereby enjoined from taking any action to prohibit either Plaintiff from performing their duties at Henderson County Community Hospital in Lexington, Tennessee, during the pendency of this action.

**IT IS SO ORDERED.**

**s/ S. Thomas Anderson**  
**S. THOMAS ANDERSON**  
**UNITED STATES DISTRICT JUDGE**

Date: December 12, 2016.